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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/580,919 | 03/02/2007 | Gilles Voydeville | 1759.221 | 8798 |
| 23405 7590 05/13/2010 HESLIN ROTHENBERG FARLEY & MESITI PC 5 COLUMBIA CIRCLE ALBANY, NY 12203 | | | EXAMINER | |
| | | | COTRONEO, STEVEN J | |
| ALBANI, NI | 12203 | ART UNIT PAPER N | | PAPER NUMBER |
| | | | 3733 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 05/13/2010 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | Application No. | Applicant(s) | | | |
|--|--|--|--------------------|--|--|--|
| Office Action Summary | | 10/580,919 | VOYDEVILLE, GILLES | | | |
| | | Examiner | Art Unit | | | |
| | | STEVEN J. COTRONEO | 3733 | | | |
| | The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1)[\ | Responsive to communication(s) filed on 11 Fe | phruary 2010 | | | | |
| | | | | | | |
| <i>'</i> — | This action is FINAL . 2b) This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| 3)[| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| | closed in accordance with the practice under Ex parte Quayre, 1935 C.D. 11, 455 O.G. 215. | | | | | |
| Dispositi | on of Claims | | | | | |
| 4)🛛 | ☑ Claim(s) <u>1-10</u> is/are pending in the application. | | | | | |
| • | 4a) Of the above claim(s) <u>10</u> is/are withdrawn from consideration. | | | | | |
| | Claim(s) is/are allowed. | | | | | |
| · | ⊠ Claim(s) <u>1-9</u> is/are rejected. | | | | | |
| · · · · · · | Claim(s) is/are objected to. | | | | | |
| | Claim(s) are subject to restriction and/or | election requirement | | | | |
| ا ال | are subject to restriction and/or | ciccular requirement. | | | | |
| Applicati | on Papers | | | | | |
| 9)□ | The specification is objected to by the Examine | r. | | | | |
| 10)⊠ The drawing(s) filed on <u>11 February 2010</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner. | | | | | | |
| , | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| | Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | |
| 11) | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority u | ınder 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 2) Notic 3) Inforr | t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other: | te | | | |

DETAILED ACTION

Newly submitted claim 10 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 10 is directed to the method of inserting an implant. No prior claim referred to a method.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 19 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marnay et al. (WO 2001/01893 provided by the applicant) see US 6,936,071 for an English version.

Marnay et al. discloses a postero-lateral intervertebral disc prosthesis (see fig 1 below) having an element (fig 1, 4) mounted with an orientation and self-centering capability (fig 1, 28) between two inserts (fig 1, 2 and 3). The first insert (fig 1, 2) has a planar section fixed on the lower vertebral plateau (fig 1, 14). The element has a lower planar surface (fig 1, 24) for support, with a limited capacity for translational displacement on the first insert and an upper surface with a generally hemispherical

Application/Control Number: 10/580,919

Art Unit: 3733

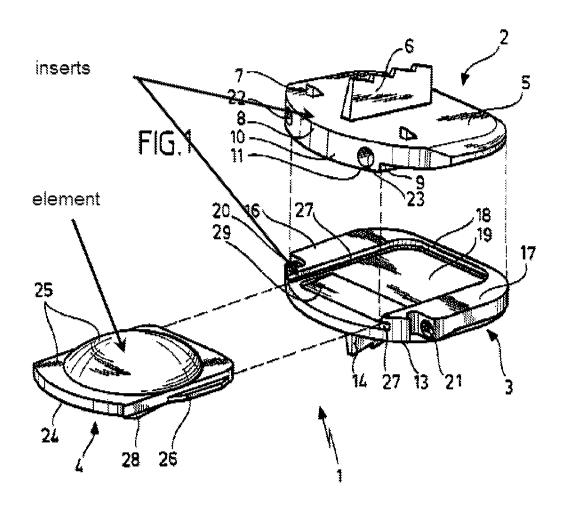
form (fig 1, 25). The second insert has a planar section (fig 1, 6) fixed on the upper vertebral plateau and opposite thereto, a concave surface (fig 7, 11) for cooperating with the hemispherical surface of the element with the possibility of multi- directional articulation. The element is a core with a positioning stud (fig 1, 28). The core has coupling means to the first insert by a clipping means (fig 1, 26 in 27) and a pivot pin (fig 1, 28). The inserts have fittings (fig 1, 20-23) for gripping and handling means. The element has fittings to engage gripping means (edge 24). A retractor is used for insertion (col. 5, II. 1-5, "spread apart... with aid of the manipulation instrument." i.e. instrument retracts). The inserts are generally circular (the implant is round, see fig 1 below).

Page 3

Marnay et al. discloses the claimed invention except for the diameter being less than 30mm and the height being about 11-15mm. The Marnay device is for insertion in the vertebral space a diameter of 30mm would allow it to fit in the space. Marnay teaches minimizing the structural height of the implant to allow for easier insertion (col. 1, II. 52-55) but does not specify the size. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the diameter less than 30mm and the height being about 11-15mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Application/Control Number: 10/580,919

Art Unit: 3733



Response to Arguments

Applicant's arguments, see remarks, filed 2/11/2010, with respect to the objection of the drawings have been fully considered. The objection of the drawing has been withdrawn due to the newly submitted clean drawings.

Applicant's arguments with respect to the objection of the specification have been fully considered. The objection of the specification has been withdrawn due to the amended specification and abstract.

Applicant's arguments with respect to the 112 rejection of claims 1-9 have been fully considered. The 112 rejection of claims 1-9 has been withdrawn due to the applicant's amendments.

Applicant's arguments with respect to the 101 rejection of claims 1-9 have been fully considered. The 101 rejection of claims 1-9 has been withdrawn due to the applicant's amendments.

Applicant's arguments filed 2/11/2010 have been fully considered but they are not persuasive. The applicant argues that it would not be obvious to make the size of the implant to have a diameter less than 30mm or a height between 11 and 15 mm. The examiner respectfully disagrees. With regard to the diameter of the implant Marnay does not specifically disclose a diameter but does disclose that the implant is meant to be placed in the disc space. The size of a disc space is about 30mm therefor it would be obvious to have the diameter of the implant to be about 30mm. The use of a postero-lateral approach is a function limitation that the device is capable of being that it can be sized to about 30mm. With respect to the height, Marnay is concerned with making the height of the implant comparable to the height of the disc space (col. 1, II. 51-55). Marnay does not give specifics about the height of the disc space. A research article written by Neil Roberts et al. discusses the lumbar disc heights in patients to be between 10 to 15mm (figure 3 of the article) (The Roberts et al. PDF is provided with the office action). Therefor it would be obvious to make the implant between 10 and 15mm to match the dimensions of the vertebral disc. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion

of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

The rejection is deemed proper.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEVEN J. COTRONEO whose telephone number is (571)270-7388. The examiner can normally be reached on M-F 730-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/580,919 Page 7

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. C./ Examiner, Art Unit 3733

/Eduardo C. Robert/ Supervisory Patent Examiner, Art Unit 3733